UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,783	10/29/2003	Richard Warby	WARB3001/REF	6091

23364 7590 02/01/2006

BACON & THOMAS, PLLC
625 SLATERS LANE
FOURTH FLOOR
ALEXANDRIA, VA 22314

EXAMINER	
DRODGE, JOSEPH W	
ART UNIT	**PAPER NUMBER**
1723	

DATE MAILED: 02/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/694,783	WARBY, RICHARD	
	Examiner	Art Unit	
	Joseph W. Drodge	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-35 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 0505.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 2-9,14-22 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In each of claims 6,8 and 18 the term "preferably" renders the respective claims and claims dependent therefrom indefinite as does "optionally" in plural recitations of claim 14.

In claim 25 the Trademark terms "type 134a or 227" is indefinite since the Instant Specification does not define what is meant by these designations in generic descriptions.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 5 of Barnes U.S. Patent No. 6,068,789 (same assignee) in view of DeCrosta et al patent 5,550,211. The instant claims are obvious generic variations of the species claims of '789, substantially differing from claim 5 of '789 only in omitting the second solvent extraction step and

reciting cleaning a polymer rather than an elastomer. However, DeCrosta in column 4, lines 34-64 teach only a single solvent extraction step using alcohol solvent and in column 2, lines 57-67, et. Seq. teaches that "elastomer" generally refers to polymers.

Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of Barnes U.S. Patent No. 6,241,828 (same assignee and similar in scope to Barnes '789) in view of DeCrosta et al patent 5,550,211. The instant claims are obvious generic variations of the species claims of '789, substantially differing from claim 5 of '789 only in omitting the second solvent extraction step and reciting cleaning a polymer rather than an elastomer. However, DeCrosta in column 4, lines 34-64 teach only a single solvent extraction step using alcohol solvent and in column 2, lines 57-67, et. Seq. teaches that "elastomer" generally refers to polymers.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7,12,13,18-22, 29-32 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by DeCrosta et al (hereafter referred to as DeCrosta) patent 5,550,211. DeCrosta discloses a method of cleaning/purifying elastomeric and rubber polymers for articles for medical and pharmaceutical use including contacting the

articles with aliphatic alcohols and consequently discloses the corresponding apparatus/articles and method of making the claimed articles.

For claims 2 and 32, ethanol solvent is disclosed at column 4, line 46.

For claims 3 and 4, completed elastomeric articles are treated (column 1,lines 17-22).

For claims 5,12,14, 20-22 and 29-31 and 35 cleaning of gaskets (i.e. "seals"), and valves as employed in manufactured metered dose dispensing device or apparatus is disclosed at column 2, lines 28-32.

For claims 6,7 the elastomer may comprise butyl rubber (column 3, line 1).

For claims 13,29 and 35 the elastomer may comprise rubber co-polymers including polyethylene or polypropylene (column 3, lines 1-4).

For claims 14,15,18, and 19,31 impurities removed include residual cross-linking agents (column 3, lines 5-6), waxes (column 5, lines 24-26) and accelerators/process aids (column 1, lines 24-27).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8,9, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeCrosta in view of Thomas patent 6,234,362. For claims 14 and15, impurities removed in DeCrosta include residual cross-linking agents (column 3, lines 5-6), waxes (column 5, lines 24-26) and accelerators/process aids (column 1, lines 24-27) used in product manufacturing.

Claims 8 and 9 and 14-17 differ in requiring the elastomeric rubber polymer to be isobutylene or co-polymer therof. Thomas teaches such at column 1, lines 44-54. It would have been obvious to one of ordinary skill in the art to have selected isobutylene or copolymer as the elastomer used in Decrosta in view of the superior sealing properties and extended shelf life of products comprising isobutylene.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeCrosta in view of Barnes patent '828. Claims 10 and 11 differ in requiring the

cleaning to occur before final product assembly. However such is taught by Barnes '828 at column 1, lines 49-53. It would have been also obvious to have cleaned the DeCrosta articles before final assembly into completed products, as taught by '828 , to assure that all contamination, inherently including contamination internal to finished product composites is removed.

Claims 23-28 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeCrosta in view of Cripps PGPUBS Document US2003/0180228. These claims all differ in requiring the completed apparatus to comprise an arrangement wherein including valve body chamber, movable or slideable valve member and a pair of annular cooperating seals at inlet and outlet apertures of the chamber. Such arrangement is taught by Cripps at figure 1 as descrivd in paragraphs 44,45 and 134-136. It would have been obvious to have utilized the DeCrosta manufacturing and cleaning process in the manufacture of the specific article arrangement taught by Cripps, since such arrangement provides an article operable to accurately and reliably dispense medicant over a relatively long article useful life.

For claims 25 and 26, both DeCrosta and Cripps teach use of fluorohydrocarbon propellants and their dispensing through the claimed products (see DeCrosta at column 1,lines 57-64).

For claims 27 and 28, dispensing of fluids including alcohols is taught by Cripps at paragraph 10, although such fluids do not constitute an article claim limitation.

Claim 34 differs from DeCrosta in requiring a moulding step in the manufacture of the seal. However, Cripps teaches moulding at paragraph 134. It would have also

been obvious to employ moulding in the manufacture of the DeCrosta seals, to enable use of fewer components in the finished articles, by producing intergrally combined components.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

January 27, 2006